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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/509,237	03/20/2000	Seth D. Rose	344-P-16-USA	9691

7590 11/17/2006

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EXAMINER
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FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 11/17/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

09/509,237

**Applicant(s)**

ROSE ET AL.

**Examiner**

Blessing M. Fubara

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 9 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>09/19/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Examiner acknowledges receipt request for extension of time, IDS, amendment and remarks filed 09/19/06. Claim 9 is pending.

#### ***Response to Arguments***

Previous rejections not reiterated herein are withdrawn.

#### ***Claim Rejections - 35 USC § 112***

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

3. Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is new matter rejection. The as filed specification does not provide support for “normally wet or moist.” There is support for “medicated films on wet or moist tissues” (specification at page 2, lines 16-18), “mucosal tissues are glabrous and initially wet” (specification at page 3, lines 2 and 2), “even on wet mucosal tissue” (specification at page 7, line 22).

This rejection may be overcome by removing the new matter from the claim.

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4. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The recitation of “normally wet or moist” is vague and indefinite because it is unclear if the tissue is wet or moist all the times or some of the times or none of the times. However, the “normally wet or moist” is examined as not wet or moist all the time keeping in mind that the language of “normally wet or moist” can also encompass dry. Clarification is respectfully requested.

***Claim Rejections - 35 USC § 103***

5. Claim 9 remains rejected under 35 U.S.C. 103(a) as being unpatentable over applicants' admitted prior art in view of Alwattari et al. (US 5,874,072).

Applicants in the specification at page 8, lines 8-19, admit of a composition comprising hydrophobe modified hydroxypropyl cellulose, water soluble polymer and ethanol that polymerizes in-situ upon application to body tissue.

However, the claim requires either carboxymethylcellulose or hydroxyethylcellulose. Alwattari discloses that hydroxypropylcellulose and hydroxyethylcellulose are equivalent as film forming polymers (column 3, lines 56-63). Claim 9 2) and 3) read on the hydrophobe modified hydroxypropylcellulose where the hydroxypropylcellulose has been substituted by hydroxyethylcellulose. One film-forming polymer can substitute for another (see equivalency of hydroxypropylcellulose and hydroxyethylcellulose in Alwattari at column 3, lines 56, 61-53 and as described above). The ethanol meets the limitation of volatile solvent. Therefore, it

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would have been obvious to one of ordinary skill in the art at the time the invention was made to use hydroxypropylcellulose modified by a compound containing hydrophobic group as the film-forming polymer. It would have been obvious to substitute the hydroxyethylcellulose polymer of Alwattari for the hydroxypropylcellulose in view of the fact that Alwattari or Rechelbacher teach hydroxypropylcellulose and hydroxyethylcellulose as equivalent film forming polymers and with the expectation that the composition will form a film upon application of the composition to a body tissue.

### *Response to Arguments*

6. Applicant's arguments filed 9/19/06 have been fully considered but they are not persuasive.

Applicant argues that the rejection is in error because "an ordinary person skilled in the art would not look to the alternatives discussed in Alwattari or Rechelbacher to combine with Pomerantz reference, since the film forming compounds in Alwattari and Rechelbacher are intended to be used in dry environment rather than applicant's claimed wetted or moist environment." Furthermore, applicant states that Pomerantz teaches away from the combination of Alwattari or Rechelbacher with Pomerantz because Pomerantz states "hydroxyethyl cellulose was unsuitable for use as substitute for hydroxypropyl cellulose.

The Alwattari reference US 5,874,072

Applicant argues that Alwattari "does not disclose or suggest modifying the water solubility of the polymer from the Applicant's group by attaching the hydrophobic group

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of the compound containing the hydrophobic group to the water soluble polymer to produce a water insoluble interaction product. Furthermore, Alwattari does not suggest that the polymers are equivalent when the hydrophobic group has been added.” That Alwattari’s compositions are used on the normally dry face or eyelashes that do not present difficulties of forming a film in situ and Alwattari does not suggest or disclose that the composition would be capable of forming a film that would adhere to wet or moist body tissue.

**Response:**

The rejection was over applicant’s admitted prior art, that is admission that hydrophobe modified polymer, which is soluble in ethanol, polymerizes in situ upon application to body tissue. This admission does not specifically state that the tissue is wet or moist or dry and the broad mention of tissue encompasses dry, moist or wet conditions of the tissue. Furthermore, the recitation of “normally wet or moist” conveys that the tissue is sometimes dry and sometimes wet or moist and not always wet or moist.

Specifically, Alwattari is relied upon for disclosing that hydroxypropyl cellulose and hydroxyethyl cellulose are both film forming polymer. However, Alwattari’s composition comprises water-insoluble polymeric material, water-soluble film forming polymers and optional ingredients such as oils and fats, emulsifiers, waxes, pigments and miscellaneous ingredients such as silica, preservatives, EDTA and imidazolidinyl urea (column 2, lines 10-15 and 20; column 3, lines 27, 55, 60-63; column 4, lines 22, 31, 63; column 5, lines 26, 64; and column 6, line 41). The compound containing a hydrophobic group of claim 9 3) reads on water insoluble polymeric materials such as aromatic diamines, terephthaloyl halides, olefinic polyols, glycidyl

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derivatives of alkyl esters of unsaturated carboxylic acids, etc (column 2, lines 35-55). Claim 9 is not a process for modification of HEC or carboxymethylcellulose and therefore, the prior art does not have to disclose modification of HEC to meet the claim. Further, the modification process disclosed in the instant specification relies on mixing the polymer with solvent and with the compound containing the hydrophobic group (instant Example 1). Mixing of the components is also envisaged in Alwattari in order to form the composition. It is further noted that no specific compound containing hydrophobic group is claimed, which means that any compound having a hydrophobic group is applicable. Alwattari discloses film-forming polymers that are combined with water-insoluble polymers in a composition and Alwattari does not exclude any of the film-forming water-soluble polymers from the composition.

Pomerantz was used in the rejection that is not reiterated herein.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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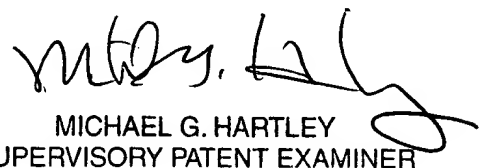
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 5:30 p.m. (Monday to Thursday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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